510k Premarket Notification Intra medulary implants MEMOMETAL TECHNOLOGIES	

JUL 26 2007

CONFIDENTIAL

SECTION 5: 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

Submitter	MEMOMETAL TECHNOLOGIES Campus de Ker Lann - Rue Blaise Pascal 35170 BRUZ – France Phone : + 33 (0)2 99 05 50 66 Fax :+ 33 (0)2 99 05 95 62
Contacts	Gilles AUDIC Quality Manager Bernard PRANDI General Manager e-mail: gilles.audic@memometal.com bernard.prandi@memometal.com
Preparation date	02/26/2007
Trade Name	MEMOMETAL INTRAMEDULARY ARTHRODESIS DEVICE (SMART TOE & X-FUSE)
Common Name	INTRAMEDULARY BONE FASTENER
Classification Name	Smooth or threaded metallic bone fastener
Legally marketed predicate devices	K022599 NEWDEAL K-Wire K964226 MEMORY STAPLE (LANDOS – DEPUY Inc)
Description	MEMOMETAL INTRAMEDULARY MEMORY BONE FASTENER are single-use bone fixation appliances intended to be permanently implanted. Intramedulary memory bone fastener are a "double X-shape K-Wire" made of shape memory nickel titanium alloy.
Intended Use	The MEMOMETAL INTRA MEDULLARY BONE FASTENER (SMART TOE / X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusion
Indication for use	Inter-digital fusion of fingers and toes and small bones fusion
Performance data	The MEMOMETAL INTRAMEDULARY MEMORY BONE FASTENER (SMART TOE & X-FUSE) conform to ASTM F564-02 (2006) Standard Specification and Test Methods for Metallic Bone Staples and to ASTM F2063-05 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.

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Substantial equivalence	The MEMOMETAL INTRAMEDULARY MEMORY BONE FASTENER (SMART TOE & X-FUSE) are substantially equivalent to their predicate device K-WIRE in terms of intended use and indications for use, design and function and their predicate device MEMORY STAPLE in term of material. Any minor differences between these two devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2007

Memometal Technologies
% Mr. Bernard Prandi
General Manager
Campus de Ker Lann - Rue Blaise Pascal
Bruz, France F35170

Re: K070598
Trade/Device Name: Memometal Intramedulary Arthrodesis Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: June 18, 2007
Received: June 21, 2007

Dear Mr. Prandi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070598

Device Name: MEMOMETAL INTRA MEDULARY BONE FASTENER (SMART TOE & X-FUSE)

Indications for Use:

The MEMOMETAL INTRA MEDULLARY BONE FASTENER (SMART TOE / X-FUSE) are indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusion

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burns

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070598